

Remarks/Arguments

Favorable consideration of this application is respectfully requested in view of the above amendment and the following remarks.

Claims 1-16 are pending in the application. Claims 1-16 have been rejected. Claims 7, 8, 13 and 16 have been amended and claim 12 has been cancelled without prejudice. New claims 17-19 have been added. Support for the language of new claims 17-19 can be found in the specification on page 6, lines 14-20. No new matter has been added.

Claims 7-8 have been objected to. The Examiner contends that in claim 7 a character appears to be missing between “80” and “g/day” and claim 8 is missing a period.

In response, claim 7 has been amended to recite “ 80 $\mu\text{g/day}$ ” and claim 8 has been amended to include a period.

In view of the above, withdrawal of the objections to claims 7-8 is respectfully requested.

Claim 16 has been rejected under 35 U.S.C. §112, first paragraph. The Examiner contends that the specification, while being enabling for treating sexually transmitted diseases, does not reasonably provide enablement for prevention of sexually transmitted diseases.

To facilitate prosecution while not necessarily agreeing with the grounds for this rejection, claim 16 has been amended to delete the phrase “and/or prevent.”

In view of the above, withdrawal of the rejection of claim 16 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claim 12 has been rejected under 35 U.S.C. §112, second paragraph. The Examiner contends that the phrase “wherein the drug delivery system does not need special storage and transportation conditions at a temperature below room temperature” is vague and indefinite.

In response, claim 12 has been cancelled without prejudice.

In view of the above, withdrawal of the rejection of claim 12 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-16 have been rejected under 35 U.S.C. §102(b) as being anticipated by EP0876815 (EP'815). With respect to EP'815 the Examiner states *inter alia*:

“The progestogenic compound is dissolved in the core polymer in a relatively low degree of supersaturation, preferably being about 1 to about 6 times of the amount of weight necessary for obtaining the saturation concentration of said progestogenic steroid in said core polymer at 25°C...The Examiner is interpreting a core wherein the progestogenic compound is dissolved at about 1 times the amount of weight necessary for obtaining the saturation concentration at 25°C, as disclosed by '815, to reasonably encompass values “up to a concentration below the saturation level at 25°C, as required by the Instant Claims (see '815, example 1). In addition, '815 discloses that an essential element of the patent invention is to have the progestogenic steroid dissolved in the core material in a relatively low degree of supersaturation and the importance of keeping the steroid dissolved in a low concentration to improve the shelf life....”

Applicants respectfully disagree with the Examiner's conclusion and submit that claims 1-16 are not anticipated by EP'815 for the reasons stated below.

As is acknowledged by the Examiner, EP'815 describes that an essential element of the invention is to have the progestogenic steroid dissolved in the core material in a relatively low degree of supersaturation (page 4, ln 6-7; claim 1). That the progestogenic steroid is dissolved in the core material in a relatively low degree of supersaturation is apparent throughout EP'815 [(the invention retains the progestogenic steroid in a supersaturated state during prolonged storage (emphasis added by underline; see p.3, ln 12-13), wherein the progestogenic compound is present in the core polymer in a relatively low degree of supersaturation, preferably being 1 to about 6 times (p. 3, ln 1; p.3, ln 9; p.3, ln 51; p.4; ln 8) of the amount necessary for obtaining its saturation level.]

EP'815 indicates that this “relatively low degree of supersaturation may generally be defined as the amount of progestogenic steroid that is one to about six times the amount necessary to obtain the saturation concentration of the steroid in the polymer at 25°C.” (see page 4, ln 7-8) The definition in Merriam-Webster's Dictionary,

Tenth Addition, page 1183 (a copy of which is attached hereto) of “supersaturate” as “to add to beyond saturation, together with the definition of “relatively low degree of supersaturation” provided in EP’815 supports that the progestogenic steroid dissolved in the core material in a degree of supersaturation means that the solution contains at least the amount by weight necessary for obtaining the saturation concentration of said steroid, i.e. said steroid is present in the core material in a concentration of at least the saturation level.

Even a relatively low degree of supersaturation is a degree of supersaturation. What is meant by “a relatively low” degree of supersaturation is further clear from the examples. Taking the saturation level of etonogestrel at 25 °C in Evatane® 28-25 of 0.35 % (p. 5, ln 19-21), it can be seen that in ‘815 the relatively low degree of supersaturation level in Example 1 is 0.57/0.35 (i.e. 1.6) ; in Example 2 0.75/0.35 (i.e. 2.1) and in Example 3 (Table 1) ranging from 0.57/0.35 to 0.75/0.35.

While claim 4 of EP’814 indicates “about one but not more than about 6 times”, EP’815 as a whole teaches that supersaturation means that the progestogenic compound is present in the core material in a concentration of at least the saturation level, whereas the present invention requires that the concentration of the progestogenic compounds is below the saturation level at 25°C. For a reference to anticipate, it must identically describe all the elements of the claimed invention. Since EP’815 describes progestogen at a low degree of supersaturation and at the very least saturated and the present invention recites that the concentration of progestogenic compound is below saturation, EP’815 does not identically describe all the elements of the present invention, and thus does not anticipate independent claim 1.

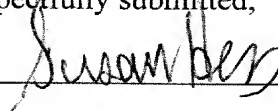
In view of the above, withdrawal of the rejection of claims 1-16 under 35 U.S.C. §102(b) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

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